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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,711	07/27/2001	Rathbun Rhodes	1146-8	8240

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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,711	RHODES ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-15,21-28 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12-15, 21-28, 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

2005 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al 6001067 in view of McIvor et al 6360888. Shults et al shows a glucose sensing device including a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. The area of the counter and working electrodes appears to be the same. In addition, the device includes a cell disruptive member, i.e. angiogenic layer around its periphery. However, McIvor shows in figure 15, a 3 electrode system for measuring glucose concentration, where the counter electrode is made larger than the working. Therefore, it would have been obvious to modify Shults et al to use such an arrangement of working and counter electrodes, as it is merely the substitution of one known equivalent sensor arrangement for another. The examiner notes that McIvor does not disclose the relative sizes of the electrodes. However, it is the examiner's position that the exact relative sizes within the parameters given in column 9, lines 1-19 of McIvor would have been a mere matter of design choice for one skilled in the art, absent a showing of unexpected results. The multi-layer membrane includes (from farther away to adjacent to electrodes) an angiogenic layer which is equivalent to the

disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and a electrolyte (i.e. hydrogel layer). The examiner notes that with respect to claim 6, the first domain is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62- column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of McIvor et al as applied to claims 1, 2, 5-10, 12-15, and 22-33 above, and further in view of Schulman et al 6119028. Shults does not teach a material for the resistance layer. However, Schulman shows a membrane 24 that behaves in the same manner of the resistance layer. Membrane 24 of Schulman is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, it would have been obvious to modify Shults to make the resistance layer from silicone, as it is merely the substitution of one known material for another. Hence, membrane 24 is an oxygen antenna. With respect to claim 7, membrane 24 is a glucose exclusion membrane

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of McIvor et al as applied to claims 1,2, 5-10, 12-15, and 22-33 above, and further in view of Ward et al et al. Ward et al shows an analyte sensing device with a

ceramic housing. Hence, it would have been obvious to modify Shults et al to use ceramic, as it is merely the substitution of one known equivalent material for another.

Applicant's arguments filed 6/15/2006 have been fully considered but they are not persuasive.

Applicant has shown unexpected results for making the counter electrode 6 times larger than the working electrode. However, the claim recites that the counter electrodes is at least 6 times greater. Applicant has not shown unexpected results for the range recited in the claim. Therefore, the unexpected results are not commensurate with the scope of the claim. If applicant were to establish unexpected results for 6 and above, the rejection would be overcome.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
August 30, 2006

ROBERT L. NASSER
PRIMARY EXAMINER